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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: David WALLACH et al

Application No.: 09/445,223 Conf. No. 9660

Filed: February 22, 2000

For: MODULATORS OF INTRACELLULAR INFLAMMATION, CELL DEATH, AND ...

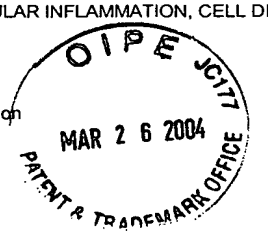
Art Unit: 1642

Examiner: M. Davis

Washington, D.C.

Atty.'s Docket: WALLACH=24

Date: March 26, 2004



THE COMMISSIONER OF PATENTS
2011 South Clark Place, Mail Stop Petition
Crystal Plaza Two, Lobby, Room 1B03
Arlington, VA 22202

Sir:

Transmitted herewith is a [ ] Amendment [XX] PETITION UNDER 37 C.F.R. §1.144 in the above-identified application.

[ ] Small Entity Status: Applicant(s) claim small entity status. See 37 C.F.R. §1.27.

[ ] No additional fee is required.

[XX] The fee has been calculated as shown below:

	(Col. 1) CLAIMS REMAINING AFTER AMENDMENT		(Col. 2) HIGHEST NO. PREVIOUSLY PAID FOR	(Col. 3) PRESENT EXTRA EQUALS	SMALL ENTITY RATE	SMALL ENTITY ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY ADDITIONAL FEE
TOTAL	* 23	MINUS	** 39	0	x 9	$		x 18	$
INDEP.	* 1	MINUS	*** 3	0	x 43	$		x 86	$
FIRST PRESENTATION OF MULTIPLE DEP. CLAIM					+ 145	$		+ 290	$
					ADDITIONAL FEE TOTAL	$	OR	TOTAL	$

* If the entry in Col. 1 is less than the entry in Col. 2, write "0" in Col. 3.

** If the "Highest Number Previously Paid for" IN THIS SPACE is less than 20, write "20" in this space.

*** If the "Highest Number Previously Paid for" IN THIS SPACE is less than 3, write "3" in this space.

The "Highest Number Previously Paid For" (total or independent) is the highest number found from the equivalent box in Col. 1 of a prior amendment of the number of claims originally filed.

[ ] Conditional Petition for Extension of Time
If any extension of time for a response is required, applicant requests that this be considered a petition therefor.

[ ] It is hereby petitioned for an extension of time in accordance with 37 CFR 1.136(a). The appropriate fee required by 37 CFR 1.17 is calculated as shown below:

Small Entity			Other Than Small Entity		
Response Filed Within			Response Filed Within		
[ ]	First	- $ 55.00	[ ]	First	- $ 110.00
[ ]	Second	- $ 210.00	[ ]	Second	- $ 420.00
[ ]	Third	- $ 475.00	[ ]	Third	- $ 950.00
[ ]	Fourth	- $ 740.00	[ ]	Fourth	- $ 1480.00
Month After Time Period Set			Month After Time Period Set		

[ ] Less fees ($_____) already paid for ___ month(s) extension of time on _____.

[ ] Please charge my Deposit Account No. 02-4035 in the amount of $_____.

[XX] Credit Card Payment Form, PTO-2038, is attached, authorizing payment in the amount of $ 130.00.

[ ] A check in the amount of $_____ is attached (check no.).

[XX] The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection with this application or credit any overpayment to Deposit Account No. 02-4035. This authorization and request is not limited to payment of all fees associated with this communication, including any Extension of Time fee, not covered by check or specific authorization, but is also intended to include all fees for the presentation of extra claims under 37 CFR §1.16 and all patent processing fees under 37 CFR §1.17 throughout the prosecution of the case. This blanket authorization does not include patent issue fees under 37 CFR §1.18.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket: WALLACH=24

In re Application of:	)	Conf. No.: 9660
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David WALLACH et al	)	Art Unit: 1642
	)	
Appln. No.: 09/445,223	)	Examiner: M. Davis
	)	
Filed: December 6, 1999	)	Washington, D.C.
	)	
For: MODULATORS OF INTRACELLULAR INFLAMMATION CELL DEATH, AND ...	)	March 26, 2004

PETITION UNDER 37 C.F.R. §1.144

Honorable Commissioner for Patents
U.S. Patent and Trademark Office
2011 South Clark Place
Mail Stop Petition
Crystal Plaza Two, Lobby, Room 1B03
Arlington, VA 22202

Sir:

In accordance with 37 C.F.R. §1.144 and pursuant to 37 C.F.R. §1.181(a)(2), applicant hereby petitions the Director to review the unity of invention requirement adhered to by the examiner in this case. As this petition is being filed not later than appeal or allowance, it is being timely submitted. The most recent request for reconsideration of the restriction requirement was submitted in applicant's amendment of October 7, 2003, at page 11.

STATEMENT OF FACTS INVOLVED

The present application is a national phase application under 35 U.S.C. §371 of international application No. PCT/IL98/00255, designating the United States. Thus, pursuant to 37 C.F.R. §1.499, the unity of invention rules set forth in 37 C.F.R. §1.475 are applicable to this case.

As originally filed, the present application included claim 1, drawn to a DNA sequence, and claim 9, drawn to a protein. Claims 1 and 9, as amended by a preliminary amendment filed with the national stage filing, read as follows:

> 1. A DNA sequence encoding a B1 protein, isoforms, fragments, or analogs thereof, said B1 protein, isoforms, fragments or analogs thereof being capable of interacting with intracellular mediators or modulators of inflammation, cell death or cell survival pathways directly or indirectly, said B1 protein, isoforms, fragments or analogs being intracellular modulators of said intracellular inflammation, cell death and/or cell survival pathways.
>
> 9. A B1 protein, isoforms, fragments, functional analogs and derivatives thereof, encoded by a DNA sequence according to claim 1, said protein, isoforms, fragments, analogs and derivatives thereof being capable of modulating the intracellular inflammation, cell death or cell survival pathways, directly or indirectly by association with other intracellular modulators or mediators of these pathways.

On March 28, 2001, a restriction requirement was issued holding lack of unity of invention, among other groups not being petitioned hereby, between Group I including, *inter alia*, claim 1 and Group II including, *inter alia*, claim 9. The examiner stated that Group I, drawn to a DNA sequence encoding B1 protein, and a method of use of said DNA sequence, forms a single inventive concept. The examiner stated that Group II is drawn to an additional product and that the "protein ... of Group II ... , [is] structurally distinct from the DNA molecule of Group I."

On May 29, 2001, claims 1 and 9 were deleted in favor of new independent polypeptide claim 40 and new DNA claim 44. Claims 40 and 44 as presented by the amendment of May 29, 2001, read:

> 40. A polypeptide which directly or indirectly potentiates cell death, said polypeptide consisting of:
>
> (a) a sequence comprising SEQ ID NO:1;
>
> (b) a sequence comprising an analog of (a) having no more than ten changes in the amino acid sequence of (a), each said change being a substitution, deletion or insertion of a single amino acid, which analog potentiates cell death;
>
> (c) a fragment of the sequence of SEQ ID NO:1, which fragment potentiates cell death; or
>
> (d) a derivative of (a), (b) or (c).

44. A DNA sequence encoding a polypeptide in accordance with claim 40.

In response to the restriction requirement, applicant elected Group I drawn to DNA, including the species of DNA encoding the B1 protein and fragments thereof. However, the election was explicitly made with traverse, pointing out that for the purpose of the restriction requirement, the examiner had conceded that the B1 protein was novel, as is the DNA encoding the protein, and therefore the special technical features shared by all of the claims of the present case relates to the novel B1 protein and the activity thereof. It was pointed out that it was inappropriate under PCT Rule 13.1 and particularly PCT Administrative Instructions, Annex B, Unity of Invention, Part II, Examples Concerning Unity of Invention, Example 17, to restrict between a protein and the DNA sequence encoding that protein. It was pointed out that this example states:

> Expression of the DNA sequence in a host results in production of a protein which is determined by the DNA sequence. The protein and the DNA sequence exhibit corresponding special technical features. Unity between claims 1 and 2 is accepted.

In the ensuing Official Action of August 28, 2001, the examiner maintained the restriction requirement, stating:

> B1 protein is an additional product, wherein the structure of B1 protein is patentably distinct from the structure of a DNA sequence encoding B1 protein. Thus, it is appropriate to separate B1 protein as a separate group.

In applicant's following amendment of February 28, 2002, applicant asked the examiner to explain why she was ignoring PCT Administrative Instructions, Annex B, Unity of Invention, Part II, Examples Concerning Unity of Invention, Example 17, which expressly states with respect to the propriety of restriction between a first claim directed to a DNA sequence and a second claim directed to the protein encoded thereby, that expression of the DNA sequence in a host results in production of a protein which is determined by the DNA sequence and, therefore, the protein and the DNA sequence exhibit corresponding special technical features and unity between the two claims is accepted. It was pointed out that these administrative instructions may not be disregarded by examiners. It was further pointed out that the examiner's comments may be applicable to restriction requirements under U.S. restriction practice, but not under PCT unity of invention practice applicable to this case.

In the amendment of February 28, 2002, in response to the examiner's rejection of claim 44 as depending from a non-elected claim, claim 44 was amended to appear in independent form and claim 40 was amended to appear in

dependent form. Thus, as amended on February 28, 2002, claims 44 and 40 read as follows:

> 40. A polypeptide which potentiates cell death, said polypeptide consisting of an amino acid sequence encoded by a DNA sequence in accordance with claim 44, or a derivative thereof.
>
> 44. A DNA sequence encoding a polypeptide which potentiates cell death, said polypeptide consisting of:
>
> (a) a sequence comprising SEQ ID NO:1;
>
> (b) a sequence comprising an analog of (a) having no more than ten changes in the amino acid sequence of (a), each said change being a substitution, deletion or insertion of a single amino acid, which analog potentiates cell death; or
>
> (c) a fragment of the sequence of SEQ ID NO:1, which fragment potentiates cell death.

In the ensuing Official Action of May 22, 2002, the examiner again disregarded the PCT Administrative Instructions and stated with respect thereto:

> This is not found to be persuasive, because the structure of the claimed polynucleotides and the encoded B1 protein is different, and thus could not constitute shared special technical features.

The restriction requirement was deemed proper and made final.

In applicant's amendment of August 22, 2002, applicant drew the examiner's attention to MPEP §1893.03(d) concerning unity of invention in PCT national stage

applications, which section specifically notes Examples 1-17 of Annex B, Part II of the PCT Administrative Instructions. It was pointed out that examiners are required to follow the MPEP, and accordingly the protein claims must be examined with the DNA claims. Claims 40 and 44 were again amended to specify that the polypeptide and the DNA sequence are isolated. Thus, following the amendment of August 22, 2002, claims 40 and 44 read as follows:

> 40. An isolated polypeptide which potentiates cell death, said polypeptide consisting of an amino acid sequence encoded by a DNA sequence in accordance with claim 44, or a derivative thereof.
>
> 44. An isolated DNA sequence encoding a polypeptide which potentiates cell death, said polypeptide consisting of:
>
> (a) a sequence comprising SEQ ID NO:1;
>
> (b) a sequence comprising an analog of (a) having no more than ten changes in the amino acid sequence of (a), each said change being a substitution, deletion or insertion of a single amino acid, which analog potentiates cell death; or
>
> (c) a fragment of the sequence of SEQ ID NO:1, which fragment potentiates cell death.

In the ensuing Official Action of November 5, 2002, the examiner again refused to follow the requirements of MPEP §1893.03(d) stating, with respect to Example 17 of Annex B Part II of the PCT Administrative Instructions:

> [S]ince it is only an example, there is no indication or disclosure that it is a requirement to consider protein X and the encoding DNA sequence together, especially in view of the fact that the protein and the encoding DNA sequence do not share a common structure.

In applicant's amendment of March 5, 2003, applicant pointed out to the examiner that DNA and the corresponding protein sequence never share a common structure. Neither do a key and a corresponding lock. However, the PCT Administrative Instructions clearly indicate that a key and a lock share a common special technical feature, and also a protein and the corresponding DNA share a corresponding special technical feature. It was pointed out that the authors of Example 17 must have understood that DNA and the corresponding protein can never share a common structure. It was again argued that the examiner must follow this example.

Finally, in the Official Action of May 7, 2003, after erroneously maintaining that Example 17 was inapplicable for four office actions, the examiner reconsidered and agreed that Example 17 should be applied to particular cases claiming a protein X and DNA encoding protein X. The examiner stated, however, that Example 17 could not be applied for the instant application, and claims 40-43, drawn to the B1 protein are not to be rejoined with the presently examined B1 polynucleotide claims because:

1) The claims of the instant application are not drafted in the format of Example 17, i.e. in Example 17, the claims are drawn to a) a protein X and b) DNA sequence encoding protein X, whereas in the instant application, the claims are drawn to a) a DNA sequence comprising SEQ ID NO:2, and b) a protein encoded by a DNA sequence comprising SEQ ID NO:2.

2) The encoded proteins of claims 40-43 could have several forms of proteins, the structure of which does not share the same or common property with the encoding DNA sequence comprising SEQ ID NO: 2, or with the antisense of part of a mRNA sequence corresponding to said DNA sequence. Thus the encoded proteins and the claimed encoding DNA sequence comprising SEQ ID NO: 2 or the antisense of part of an mRNA sequence corresponding to said DNA sequence do not share the same technical feature.

3) According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The claimed polynucleotide sequence encoding an analog or a fragment of the encoded protein, which analog or fragment potentiates cell death do not share the same technical feature with the encoded protein, which analog or fragment potentiates cell death do not share the same technical feature with the encoded protein, because potentiating cell death is an activity known for several proteins in the art, such as BAX or various caspases (see specification on page 6, last paragraph, and page 7, last paragraph, bridging page 8), and thus potentiating cell death is not a contribution over the prior art and is not considered a special technical feature.

In applicant's following amendment of October 7, 2003, claim 40 was amended to appear in independent form, using the same language as used in the DNA claim with respect

to the polypeptide encoded thereby. Thus, the form of claims 40 and 44 which presently appear in this case is as follows:

> 40. An isolated polypeptide which potentiates cell death, said polypeptide consisting of:
>
> (a) a sequence comprising SEQ ID NO:1;
>
> (b) a sequence comprising an analog of (a) having no more than ten changes in the amino acid sequence of (a), each said change being a substitution, deletion or insertion of a single amino acid, which analog potentiates cell death; or
>
> (c) a fragment of the sequence of SEQ ID NO:1, which fragment potentiates cell death.
>
> 44. An isolated DNA sequence encoding a polypeptide which potentiates cell death, said polypeptide consisting of:
>
> (a) a sequence comprising SEQ ID NO:1;
>
> (b) a sequence comprising an analog of (a) having no more than ten changes in the amino acid sequence of (a), each said change being a substitution, deletion or insertion of a single amino acid, which analog potentiates cell death; or
>
> (c) a fragment of the sequence of SEQ ID NO:1, which fragment potentiates cell death.

In the amendment of October 7, 2003, applicant argued that claim 40 had now been amended so as to appear as an independent claim directed to protein X, wherein X is

defined in paragraphs a, b and c, and that claim 44 is directed to a DNA sequence encoding protein X, wherein protein X has the exact same definition as set forth in claim 40. Accordingly, the present claims use the same formula as is approved in Example 17, and the examiner should now examine both the DNA and the protein claims.

In the examiner's action of January 15, 2004, the examiner again did not find applicant's arguments to be persuasive, stating:

> The restriction requirement has not and will not change in view of the claim amendment, and protein claims are not rejoined with DNA claims, because the restriction requirement is based on the claims as originally presented at the time of the restriction requirement.

The present petition is being taken from this final restriction requirement.

POINTS TO BE REVIEWED AND ACTION REQUESTED

It is requested that the Director review the examiner's position that the claims as presently amended must be ignored when reconsidering a restriction requirement based on unity of invention, and that the propriety of the restriction requirement must be based on the claims as originally presented at the time of the restriction requirement. Alternatively, it is requested that the Director

review the examiner's determination that the claims as originally presented at the time of the restriction requirement do not share unity of invention.

It is requested that the Director instruct the examiner to reconsider the restriction requirement in light of the language of the claims as presently appear in the case, in which case the restriction requirement must be withdrawn, and the protein and DNA claims examined together as is required by the PCT Administrative Instructions. Alternatively, it is requested that the Director instruct the examiner to reconsider claims 40 and 44 as presented on May 29, 2001, in light of the proper standard of reviewing unity between a DNA molecule and the protein encoded thereby, and reach the determination that the restriction requirement between claims and 40 and 44 should not have been maintained at that time and must now be withdrawn.

ARGUMENT

More than 25 months after the original restriction requirement, the examiner finally conceded in the official action of May 7, 2003, that Example 17 of the PCT Administrative Instructions was applicable to this case. It should be noted that the Official Action of May 7, 2003, was a non-final Official Action. Without conceding the propriety of

the examiner's position that the form of claims 40 and 44 that were before her were not drafted in the format of Example 17, or should not be examined together in the spirit of Example 17, applicant chose to amend claim 40 so that the claims will be exactly in the form of Example 17, and thus obviate the points raised by the examiner which allegedly distinguished the present situation from the situation in Example 17 of the PCT Administrative Instructions. However, instead of finally conceding that she had been wrong from the beginning and that the DNA and protein claims should have been examined together from the beginning, the examiner stated that a restriction requirement can only be based on the claims as originally presented at the time of the restriction requirement.

The latter statement of the examiner is not found anywhere in 37 C.F.R., nor could applicant find such a statement anywhere in the MPEP. Applicant could not find it in any case law, or in *Horowitz Patent Law and Practice* or *Chisum on Patents* (by means of an electronic full text search on Lexis). Thus, this appears to either be a new policy of the Patent and Trademark Office that has not been published, or to have been simply made up by the examiner out of wholecloth. In either case, such a policy should be reconsidered and withdrawn as being inappropriate and bad public policy.

Restriction requirements are meant to prevent two patents from issuing drawn to the same invention. Thus, it is appropriate to reconsider the restriction requirement as prosecution progresses to ensure that patentable distinctness remains throughout prosecution.

Furthermore, it is common practice to review the appropriateness of a restriction requirement after claims have been found to be allowable, as is set forth in MPEP §821.04 relating to rejoinder.

Perhaps the examiner intends this new policy to apply only to unity of invention and not restriction practice. However, it is not seen why any such distinction should be made.

Furthermore, in this case the examiner's restriction requirement was wrong from the beginning, as the examiner admittedly applied the wrong considerations and repeated the erroneous interpretation of the law for two years before admitting her error. The single inventive concept here is the protein. Expression of the DNA sequence in the host results in the production of a protein which is determined by the DNA sequence, and therefore the protein and the DNA sequence exhibit corresponding special technical features and unity between DNA claims and protein claims must be accepted.

Accordingly, it is urged that the original admitted error of the examiner, which persisted for two years, not be compounded by allowing the examiner to persist in maintaining the restriction between the DNA and protein claims based upon the novel policy that restriction requirements must be based on the claims as originally presented at the time of the restriction requirement.

Alternatively, the following grounds for reversal of the examiner should be considered. The claims originally presented at the time of the restriction requirement must be considered to be the claims of May 29, 2001. These claims are in the form of Example 17. The examiner should have withdrawn the restriction requirement as requested at that time and examined the protein and DNA claims together as early as May 29, 2001. Thus, even if this new "policy" of the Patent and Trademark Office is to be endorsed by the Director, it is not applicable in this situation, as the claims as originally presented on May 29, 2001, (prior to examination on the merits of any claim) were written in such a manner that Example 17 of the PCT Administrative Instructions was applicable. Thus, the restriction requirement should have been withdrawn and claims 40 and 44 examined together at that time.

CONCLUSION

Reversal of the examiner and instruction for the examiner to examine the protein and DNA claims in this case, as they present a single special technical feature, are earnestly solicited.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
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By _____
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